

Appl. No. : 10/699,589  
Filed : October 31, 2003

### AMENDMENTS TO THE CLAIMS

1. (Currently Amended) Apparatus for achieving weight loss in a patient, comprising:

an artificial stoma device sized and configured to be installed in an esophagus or stomach of the patient;

a gastrointestinal sleeve connected to the artificial stoma device, the gastrointestinal sleeve sized and configured to extend from the artificial stoma device through the stomach and into the intestines of the patient, and

a non-tissue cuff on the stoma device to secure the stoma device at an installation site; and

means for reversibly attaching the gastrointestinal sleeve to the artificial stoma device.

2. (Original) The apparatus of Claim 1, wherein the artificial stoma device has a stoma orifice sized and configured to create a restriction to ingestion of food.

3. (Original) The apparatus of Claim 1, wherein the artificial stoma device has an adjustable stoma orifice.

4. (Original) The apparatus of Claim 1, wherein the artificial stoma device has a self-adjusting stoma orifice.

5. (Cancelled)

6. (Previously presented) The apparatus of Claim 1, further comprising a sutureless attachment mechanism for attaching the artificial stoma device within the stomach of the patient.

7. (Previously presented) The apparatus of Claim 1, wherein the gastrointestinal sleeve comprises a gastric component and an intestinal component, and at least a portion of the gastric component is impermeable.

8. (Previously presented) The apparatus of Claim 7, wherein the gastric component of the gastrointestinal sleeve is sufficiently flexible that peristaltic motion of the stomach causes movement of food through the gastric component.

9. (Previously presented) The apparatus of Claim 7, wherein the gastrointestinal sleeve additionally comprises an anchor, for anchoring the distal end of the gastric component in the region of the Pylorus.

**Appl. No.** : 10/699,589  
**Filed** : October 31, 2003

10. (Previously presented) The apparatus of Claim 7, wherein at least a portion of the intestinal component of the gastrointestinal sleeve is impermeable.

11. (Previously presented) The apparatus of Claim 1, wherein the gastrointestinal sleeve is sufficiently flexible to allow peristaltic motion of the intestinal wall to cause movement of food through an intestinal component of the sleeve.

12. (Previously presented) The apparatus of Claim 1, wherein the gastrointestinal sleeve is removably attached to the artificial stoma.

13. (Previously presented) The apparatus of Claim 1, wherein a gastric component of the gastrointestinal sleeve is removably attached to an intestinal component of the gastrointestinal sleeve.

14. (Previously presented) The apparatus of Claim 1, wherein the cuff is disposed on the outer circumference of the artificial stoma.

15. (Previously presented) The apparatus of Claim 1, further comprising a plurality of attachment points on the outer circumference of the stoma device.

16. (Previously presented) The apparatus of Claim 15, wherein the stoma device is flexible and elastic, with properties to minimize the resistance of the stoma to motion of the stomach at the attachment points.

17. (Previously presented) The apparatus of Claim 1, wherein the stoma device is sufficiently flexible that it may be collapsed to facilitate passage through the esophagus.

18. (Previously presented) The apparatus of Claim 1, wherein the stoma device comprises a fixed diameter stoma.

19. (Previously presented) The apparatus of Claim 1, further comprising attachment mechanisms for attachment of the stoma device to an installation site.

20. (Previously presented) The apparatus of Claim 19, wherein the attachment mechanisms comprise barbs, for piercing adjacent tissue.

21. (Previously presented) The apparatus of Claim 1, wherein a gastric portion of the gastrointestinal sleeve has a diameter within the range of from about 20 mm to about 30 mm.

22. (Previously presented) The apparatus of Claim 1, wherein the diameter of an intestinal component of the gastrointestinal sleeve has a diameter within the range of from about 15 mm to about 30 mm.

Appl. No. : 10/699,589  
Filed : October 31, 2003

23. (Previously presented) The apparatus of Claim 1, wherein the gastrointestinal sleeve is dimensioned such that the distal end of the sleeve may be positioned at least as far as 100 cm distal from the Pylorus.

24. (Previously presented) Apparatus for achieving weight loss in a patient, comprising:

an artificial stoma device sized and configured to be installed in a stomach of the patient;

a gastrointestinal sleeve connected to the artificial stoma device, the gastrointestinal sleeve sized and configured to extend from the artificial stoma device through the stomach and into the intestines of the patient; and

means for reversibly attaching the gastrointestinal sleeve to the artificial stoma device.

25. (Previously presented) The apparatus of Claim 24, wherein the artificial stoma device has a stoma orifice sized and configured to create a restriction to ingestion of food.

26. (Previously presented) The apparatus of Claim 24, wherein the artificial stoma device has an adjustable stoma orifice.

27. (Previously presented) The apparatus of Claim 24, wherein the artificial stoma device has a self-adjusting stoma orifice.

28. (Previously presented) The apparatus of Claim 24, further comprising a sutureless attachment mechanism for attaching the artificial stoma device within the stomach of the patient.

29. (Claims 29 through 49 Cancelled)

50. (Currently Amended) Apparatus for achieving weight loss in a patient, comprising:

a tissue attachment cuff comprising a non tissue material, sized and configured to be installed without the need for tissue plication at an attachment site in the vicinity of the gastroesophageal junction in the patient;

at least one tissue anchor for extending from the attachment cuff completely through the adjacent tissue wall at the attachment site; and

Appl. No. : 10/699,589  
Filed : October 31, 2003

a gastrointestinal sleeve connected to the cuff, the gastrointestinal sleeve sized and configured to extend from the cuff through the stomach and into the intestines of the patient;

wherein the tissue anchor is moveable from a first configuration in which it is advanceable through a delivery cannula, and a second configuration for functioning as an anchor on the serosal side of the tissue wall, the tissue anchor comprising a button shape when in the second configuration.

51. (Previously presented) The apparatus of Claim 50, wherein the attachment cuff supports a stoma orifice having a fixed size.

52. (Previously presented) The apparatus of Claim 50, wherein the attachment cuff supports a stoma orifice having an adjustable size.

53. (Previously presented) The apparatus of Claim 52, wherein the stoma orifice is self-adjusting.

54. (Cancelled)

55. (Cancelled)

56. (Cancelled)

57. (Previously presented) The apparatus of Claim 50, wherein the gastrointestinal sleeve comprises a gastric component and an intestinal component, and at least a portion of the gastric component is impermeable.

58. (Previously presented) The apparatus of Claim 57, wherein the gastric component of the gastrointestinal sleeve is sufficiently flexible that peristaltic motion of the stomach causes movement of food through the gastric component.

59. (Previously presented) The apparatus of Claim 57, wherein the gastrointestinal sleeve additionally comprises an anchor, for anchoring the distal end of the gastric component in the region of the Pylorus.

60. (Previously presented) The apparatus of Claim 57, wherein at least a portion of the intestinal component of the gastrointestinal sleeve is impermeable.

61. (Previously presented) The apparatus of Claim 50, wherein the gastrointestinal sleeve is sufficiently flexible to allow peristaltic motion of the intestinal wall to cause movement of food through an intestinal component of the sleeve.

**Appl. No.** : 10/699,589  
**Filed** : October 31, 2003

62. (Previously presented)The apparatus of Claim 50, wherein a gastric component of the gastrointestinal sleeve is removably attached to an intestinal component of the gastrointestinal sleeve.

63. (Previously presented)The apparatus of Claim 50, wherein the artificial, non tissue cuff comprises a fabric.

64. (Previously presented)The apparatus of Claim 50, further comprising a plurality of suture attachment points on an outer circumference of the cuff.

65. (Previously presented)The apparatus of Claim 50, wherein the apparatus is flexible and elastic, with properties to minimize the resistance to motion of the stomach at the attachment site.

66. (Previously presented)The apparatus of Claim 50, wherein a gastric portion of the gastrointestinal sleeve has a diameter within the range of from about 20 mm to about 30 mm.

67. (Previously presented)The apparatus of Claim 50, wherein an intestinal component of the gastrointestinal sleeve has a diameter within the range of from about 15 mm to about 30 mm.

68. (Previously presented)The apparatus of Claim 50, wherein the gastrointestinal sleeve is dimensioned such that the distal end of the sleeve may be positioned at least as far as 100 cm distal from the Pylorus.

69. (New) Apparatus for achieving weight loss in a patient, comprising:

a tissue attachment cuff comprising a non tissue material, sized and configured to be installed without the need for tissue plication at an attachment site in the vicinity of the gastroesophageal junction in the patient;

at least one tissue anchor for extending from the attachment cuff completely through the adjacent tissue wall at the attachment site, the tissue anchor configured for implantation through a delivery cannula; and

a gastrointestinal sleeve connected to the cuff, the gastrointestinal sleeve sized and configured to extend from the cuff through the stomach and into the intestines of the patient;

wherein the tissue anchor is moveable from a first configuration in which it is advanceable through the delivery cannula, and a second configuration for functioning as

**Appl. No.** : 10/699,589  
**Filed** : October 31, 2003

an anchor on the serosal side of the tissue wall, and the tissue anchor comprises an approximately 90° bend when in the second configuration, to prevent the tissue anchor from being pulled out through the tissue wall.

70. (New) The apparatus of Claim 69, wherein the attachment cuff supports a stoma orifice having a fixed size.

71. (New) The apparatus of Claim 69, wherein the attachment cuff supports a stoma orifice having an adjustable size.

72. (New) The apparatus of Claim 71, wherein the stoma orifice is self-adjusting.

73. (New) The apparatus of Claim 69, wherein the gastrointestinal sleeve comprises a gastric component and an intestinal component, and at least a portion of the gastric component is impermeable.

74. (New) The apparatus of Claim 73, wherein the gastric component of the gastrointestinal sleeve is sufficiently flexible that peristaltic motion of the stomach causes movement of food through the gastric component.

75. (New) The apparatus of Claim 73, wherein the gastrointestinal sleeve additionally comprises an anchor, for anchoring the distal end of the gastric component in the region of the Pylorus.

76. (New) The apparatus of Claim 73, wherein at least a portion of the intestinal component of the gastrointestinal sleeve is impermeable.

77. (New) The apparatus of Claim 69, wherein the gastrointestinal sleeve is sufficiently flexible to allow peristaltic motion of the intestinal wall to cause movement of food through an intestinal component of the sleeve.

78. (New) The apparatus of Claim 69, wherein a gastric component of the gastrointestinal sleeve is removably attached to an intestinal component of the gastrointestinal sleeve.

79. (New) The apparatus of Claim 69, wherein the artificial, non tissue cuff comprises a fabric.

80. (New) The apparatus of Claim 69, further comprising a plurality of suture attachment points on an outer circumference of the cuff.

**Appl. No.** : 10/699,589  
**Filed** : October 31, 2003

81. (New) The apparatus of Claim 69, wherein the apparatus is flexible and elastic, with properties to minimize the resistance to motion of the stomach at the attachment site.

82. (New) The apparatus of Claim 69, wherein a gastric portion of the gastrointestinal sleeve has a diameter within the range of from about 20 mm to about 30 mm.

83. (New) The apparatus of Claim 69, wherein an intestinal component of the gastrointestinal sleeve has a diameter within the range of from about 15 mm to about 30 mm.

84. (New) The apparatus of Claim 69, wherein the gastrointestinal sleeve is dimensioned such that the distal end of the sleeve may be positioned at least as far as 100 cm distal from the Pylorus.